

# Why hasn't FDA given full approval for COVID vaccines?

By TOM AVRIL  
The Philadelphia Inquirer

More than eight months ago, large studies found that both the Pfizer-BioNTech and Moderna COVID-19 vaccines reduced the risk of illness by more than 90%. Yet the U.S. Food and Drug Administration has not yet granted them full approval, to the dismay of public-health officials eager to boost vaccination rates as the delta variant sends infections skyward.

## So what is the holdup?

Part of the reason, according to experts in drug regulation, may be simply that the agency can afford to take the time.

In December, the FDA authorized the first two vaccines for emergency use, and did so for a third in February. Those authorizations, though based on extensive, rigorous research, are temporary in nature. Before granting permanent approval ("licensure"), the agency can spend months to make triply sure that all regulatory requirements are met, given that the vaccines are



Doses of the Moderna COVID-19 vaccine.

available for all who want them in the meantime.

Still, with the emergence of the highly transmissible delta variant of the coronavirus, public-health officials are eager for the agency to move forward, contending that full approval may pave the way for more people to be vaccinated.

That could happen in two ways. Physicians hope that if the agency licenses the drugs, some who are hesitant about vaccination may become more receptive. Even if not, more businesses and institutions may decide they have a legal basis for requiring

the shots, said Greer Donley, an assistant professor at the University of Pittsburgh Law School.

Hundreds of universities already have instituted vaccine mandates for students enrolling this fall, in one case surviving a challenge in federal court. And on Monday, the U.S. Department of Veterans Affairs announced it would require the shots for 115,000 frontline workers. But with full approval, Donley said, employers seeking to require the vaccines may feel they are on even firmer legal ground. Either way, FDA's

career civil servants, accustomed to carrying out their careful reviews in relative obscurity, are under public pressure like never before.

## What is emergency use?

The FDA's power to authorize drugs for emergency use is relatively new, enacted by Congress in 2004 in response to the anthrax attacks of 2001.

The agency can grant such an approval if it is "reasonable to believe" that the product may be effective, and that its "known and potential benefits" exceed its "known and potential risks," according to the statute.

But vaccines are not like most drugs, in that they are administered to healthy people to prevent illness, not to treat it. So when the FDA issued guidance on what it would require before authorizing vaccines against COVID-19, the agency went beyond the letter of the law.

Drug makers learned they would need to enroll tens of thousands of partic-

ipants, randomly assigning some to receive the vaccine and others to get a placebo. In short, they needed to run the type of large, well controlled trial that is required for regular approval of any vaccine, said biostatistician Susan S. Ellenberg, a professor emerita at the University of Pennsylvania's Perelman School of Medicine.

On Nov. 9, the partnership of Pfizer and BioNTech announced that its vaccine prevented more than 90% of cases of COVID-19, far exceeding most expectations.

Similar results came a week later from Moderna Inc., and by the middle of December, the FDA had authorized emergency use of both.

## What more do they need?

Before granting the emergency authorizations, the FDA analyzed the rates of any side effects for two months following administration of the vaccines.

Any side effects caused by vaccines tend to arise within a month, and physicians generally agreed that two months' of safety data was more than sufficient — especially given the urgency of curbing the pandemic during the wintertime surge.

The evidence on the COVID-19 vaccines was promising, with some participants reporting temporary consequences such as a fever, headache, or sore arm — nothing serious or long-lasting.

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